



Original article

A prospective, randomised trial of prophylactic antibiotics versus bag extraction in the prophylaxis of wound infection in laparoscopic cholecystectomy

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Septic complications are rare following laparoscopic cholecystectomy if prophylactic antibiotics are given, as demonstrated in previous studies. Antibiotic treatment may be unnecessary and, therefore, undesirable, so we compared two forms of prophylaxis: a cephalosporin antibiotic and bag extraction of the dissected gallbladder.

A total of 76 patients undergoing laparoscopic cholecystectomy were randomised to either receive an antibiotic or to have their gallbladder removed from the abdomen in a plastic bag. Complicated cases were excluded.

There was a total of 6 wound infections (7.9%), 3 in each of the study groups. All these were associated with skin commensals. There were no other septic complications.

Bacteriological studies grouped the organisms isolated from the bile and the wound as potential pathogens and likely commensals. A total of 10 potential pathogens were isolated, 9 of which were found in the group receiving antibiotics.

We conclude that septic sequelae of uncomplicated laparoscopic cholecystectomy are uncommon, but clearly not entirely prevented by antibiotic or mechanical prophylaxis. Prophylactic antibiotics may not be required in uncomplicated laparoscopic cholecystectomy. Further study is warranted.

Key words: Laparoscopic cholecystectomy – Prophylactic antibiotics – Mechanical prophylaxis – Bag extraction – Wound infection – Prospective randomised trial

Open cholecystectomy was associated with a wound infection rate ranging from 1–21%.¹ The use of prophylactic antibiotics reduced this rate to 3–7%^{2,3} and so has become common practice. Laparoscopic cholecystectomy is associated with smaller wounds and minimal tissue damage and, therefore, presumably a lower risk of wound infection. The clinical problem might be so small that no antibiotic prophylaxis is required. We adopted a practice of single-dose prophylaxis using cefuroxime and recorded a low infection rate.⁴ This suggested the possibility of abandoning the use of antibiotics for uncomplicated laparoscopic cholecystectomy. Before doing this, we felt it would be useful to compare the use of antibiotics with mechanical exclusion of the gallbladder from the umbilical wound, using a plastic bag to extract it from the abdomen.

Patients and Methods

Patients undergoing elective laparoscopic cholecystectomy were randomised to receive a single dose of cefuroxime (750 mg, i.v.) or to have the gallbladder removed from the abdomen inside a plastic bag (Endopouch, Ethicon, UK) brought out through the umbilical port. Randomisation took place after laparoscopy had established that both methods were possible and was done using a sealed envelope technique.

All patients undergoing elective cholecystectomy were entered into the trial unless they refused consent, were already taking antibiotics, or had an operative cholangiogram performed.

The operation was carried out using the 'American' technique with four ports. The skin was prepared with aqueous povidone iodine. The gallbladder was removed through the umbilical port, with or without a containing bag.

The skin wounds were closed with subcuticular Vicryl (Ethicon, UK) sutures in both the epigastrium and umbilicus and all four were covered with Bioclusive (Johnson and Johnson) dressings, which were left in place for one week.

Bacteriological swabs were taken from the umbilicus after skin preparation with povidone iodine, the open gallbladder after its removal from the abdomen and from the umbilical wound just prior to closure.

If there was contamination of the operative field by spilled bile, an antibiotic was given and the patient was withdrawn from the study.

An infection control sister followed up the patients. She was unaware of the method of prophylaxis used. A wound infection was defined as the discharge of pus from the wound with signs of inflammation present. Their further clinical management was at the discretion of the doctor seeing the patient.

The Medical Research Ethics Committee approved the study at Southmead Hospital.

Results

Clinical

A total of 106 consecutive patients (20 male, 86 female) underwent elective laparoscopic cholecystectomy in a 14-month period: 18 were excluded because of the need to carry out cholangiography and 3 because of concomitant antibiotic usage. Five were withdrawn because of spillage of the gallbladder contents into the peritoneal cavity and 4 for conversion into open operation. Thus, 76 patients entered into the study and were available for evaluation with none lost to follow-up. There were 39 in the 'antibiotic' group and 37 in the 'bag' group.

There were 6 clinically diagnosed wound infections, all at the umbilicus and 3 occurred in each of the study groups. There were no other septic complications. The average postoperative stay was 1.3 days, with no significant differences between the two groups and no delays due to septic complications.

Microbiological

The results of the peri-operative bacteriological studies were available in 68 cases. The nature of the bacteria isolated from all of the pre- and postoperative wound sites and the gallbladder are shown in Table 1. The isolates were divided into groups: 'likely commensals' (coagulase-negative *Staphylococcus* spp., *Diphtheroids*, *Propionibacterium* spp. and *Streptococcus viridans*) and 'potential pathogens' (*Staphylococcus aureus*, coliforms, anaerobes and *Pseudomonas* spp.).

The majority of potential pathogens were isolated in the 'antibiotic' group ($n = 9$) whereas only one potential pathogen was isolated in the 'bag' group: this difference is statistically significant ($P = 0.02$: chi-squared test with Yates' correction). All were sensitive to cefuroxime.

Of the 6 patients who developed postoperative wound infections, only one of the swabs isolated an

Table 1 Distribution of organisms within the study subgroups at the different swab sites

	Umbilicus	Gallbladder	Postoperative wound
'Antibiotic' group			
Potential pathogen	2	3	4
Likely commensal	18	5	16
'Bag' group			
Potential pathogen	0	1	
Likely commensal	14	4	

Table 2 Organisms isolated from patients who later developed wound infections (all coagulase-negative *Staphylococcus* spp.)

	Umbilicus	Gallbladder wound	Postoperative wound
'Antibiotic' group (n = 3)	0	0	1
'Bag' group (n = 3)	2	0	2

organism in the 'antibiotic' group, and 4 in the 'bag' group. The organisms grown were all skin commensals (coagulase-negative *Staphylococcus* spp.). The difference between the two groups was not significant, using chi-squared analysis. The distribution of the organisms isolated in these groups is illustrated in Table 2.

Discussion

The overall postoperative wound infection rate in this study was 7.9% and was equally distributed between the two study groups. The coincidence of infection at the umbilicus and the use of this site for the removal of the gallbladder implies that the two are linked. However, two findings in this study suggest this is not the case. First, the bacteriological information from this study fails to support the gallbladder as being the source of wound infection. All organisms isolated from the wound sites of those patients that developed postoperative infections were skin commensals, and there is no relationship between the peri-operative organisms isolated and the subsequent wound infection. Second, there was no difference in the rate of infection between the two study groups despite significantly more pathogens being present in the antibiotic group.

Mechanical isolation of the gallbladder from the umbilical wound appears to be as effective as prophylaxis with cefuroxime in preventing wound infection. By chance, however, there were few pathogens isolated from the gallbladders in the bag group. In the antibiotic group, pathogens were isolated in 23% of cases but did not result in infection, possibly because of adequate tissue concentrations of antibiotic.

The wound infections in this study appear to be associated with commensal organisms. It is possible that the use of a non-absorbent dressing at the umbilicus, even though apparently permeable, allows the collection of fluid which creates a favourable environment for the colonisation with skin commensals and subsequent infection. Although not part of this study, it may be that absorbent dressings at the umbilical wound site are preferable. Equally, this study does not address the use of different suture closure methods which may be relevant.

In previous studies,⁵⁻⁷ similar results were obtained with no correlation between infected bile and septic complications, suggesting that postoperative wound infections in laparoscopic cholecystectomy are independent of gallbladder organisms. This is despite the high incidence of infected bile in patients with cholelithiasis previously documented (22-46%),⁸ which is repeated in this study. These findings contradict earlier study results which demonstrated a close correlation between bile bacterial load and incidence of postoperative wound infections at open cholecystectomy. This may be because laparoscopic operation reduces the amount of tissue trauma making the wound less prone to infection.

The disadvantages of antibiotic use include cost, encouraging the emergence of resistant strains of bacteria and side-effects (including hypersensitivity and infection with *Clostridium difficile*). They should not be used without evidence of efficacy. The present study suggests that there may be no advantage to be gained from antibiotic prophylaxis in elective laparoscopic cholecystectomy where the source of infection appears to be skin commensals rather than the colonised diseased gallbladder. Although this study is inconclusive, it does suggest that further studies could reasonably include a control arm with no prophylaxis against wound infection.

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